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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/617,955	07/14/2003	Ichiro Yamashita	61352-039	4459

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EXAMINER

YU, MELANIE J

ART UNIT	PAPER NUMBER
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1641

DATE MAILED: 01/11/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/617,955

Applicant(s)

YAMASHITA, ICHIRO

Examiner

Melanie Yu

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 20 December 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-21 is/are pending in the application.
- 4a) Of the above claim(s) 14-21 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-13 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 14 July 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|----------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>7/14/03</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

1. Applicant's election without traverse of group I, claims 1-13, in the reply filed on December 20, 2004 is acknowledged. Claims 14-21 have been withdrawn from further consideration as being drawn to a non-elected invention.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 1-13 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 1 is indefinite because it is unclear if a plurality of first binding sites are binding to a other single first binding site carried by an adjacent fine particle, and if the adjacent fine particle is the same as the protein fine particles. Furthermore, it is unclear if the substitution of the condensed amino acids is a method step or if the second binding site comprises condensed amino acids, which are substituted for another entity on the protein fine particle.

Regarding claim 12 the phrase "more multivalent" is vague because it is unclear if the cation can be multivalent or is more than multivalent.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are

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such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

3. Claims 1-11 and 13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nagayama et al. (Fabrication and control of Two-Dimensional Crystalline Arrays of Protein Molecules, Jpn. J. Appl. Phys. 1995:34; 3947-3954) in view of Onda et al. (US 6,107,084).

Nagayama et al. teach a fine particle film comprising: a positively charged substrate (ion bombardment, pg. 3949, right column, last sentence) and a plural number of fine protein particles (pg. 3948, left column, lines 29-31) arranged on the surface of the substrate in a plane direction parallel to the surface of the substrate (perpendicular to crystal plane is parallel to substrate; pg. 3953, left column, lines 5-7), wherein each of the protein fine particles has a plural number of first binding sites which binds to the first binding site carried by another adjacent fine particle (pg. 3949, left column, lines 3-7; pg. 3953, right column, lines 14-22) and each of the first binding sites comprising condensed amino acids (pg. 3953, right column, lines 14-22).

Nagayama et al. fail to teach one or more second binding sites which binds to the substrate comprising condensed amino acids, and at least a part of the condensed amino acids constituting the second binding site are substituted.

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Onda et al. teach a binding site of protein fine particles bound to a substrate comprising substituted condensed amino acids through electrostatic interactions (col. 3, line 67 – col. 4, lines 1-4; col. 4, lines 57-67), in order to provide a method to immobilize and assemble multiple species of different proteins in a desired order.

Therefore it would have been obvious to one having ordinary skill in the art at the time the invention was made to include in the film of Nagayama et al., a second binding site for the substrate comprising condensed amino acids as taught by Onda et al., in order to avoid decreased productivity and difficult handling involved with the immobilization of proteins through the transfer of protein films to a substrate from the surface of a liquid.

Regarding claims 2 and 4, Onda et al. teach at least a part of the condensed amino acids constituting the second binding site is a basic amino acid (amino groups comprise basic amino acids; col. 4 line 57 – col. 5, line 12).

With respect to claim 3, Onda et al. teach the substrate being negatively charged (col. 6, lines 29-31).

With respect to claim 6, Nagayama et al. teach the plurality of protein fine particles arranged regularly on the surface of the substrate (pg. 3947, left column, lines 2-11).

Regarding claims 7-11 and 13, Nagayama et al. teach each of the protein fine particles being apoferritin and having a 2-, 3-, or 4-times symmetric axis (pg. 3951, left column, lines 12-23).

4. Claim 12 is rejected under 35 U.S.C. 103(a) as being unpatentable over Nagayama et al. in view of Onda et al. further in view of Takeda et al. (Control of Crystal Forms of Apoferritin by Site-Directed Mutagenesis, *Proteins: Structure, Function, and Genetics*, 1995:23; 548-556).

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Nagayama et al. in view of Onda et al., as applied to claim 10 above, teaches a fine particle film, but fail to teach two adjacent fine particles binding via an ionic bond with a cation.

Takeda et al. teach each of the first binding sites carried by adjacent two fine particles binding via an ionic bond with a cation which is divalent being sandwiched there between (pg. 554, left column, lines 7-11; pg. 554, right column, 2nd paragraph, lines 1-4), in order to produce good crystals for crystallographic study.

Therefore it would have been obvious to one having ordinary skill in the art at the time the invention was made to include in the fine particle film of Nagayama et al., binding via an ionic bond with a divalent cation as taught by Takeda et al., in order to provide stabilized ion bridges between recombinant L-apoferritin molecules.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Melanie Yu whose telephone number is (571) 272-2933. The examiner can normally be reached on M-F 8:30-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on (571) 272-0823. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Melanie Yu
Patent Examiner
Art Unit 1641



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01/05/05